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Compliance with Controlled Substances & Dangerous Drugs in Research Projects

Ask RCRA-September 19, 2024



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**Research Compliance
and Regulatory Affairs**

Research Administration

In this presentation

- What means to be “in compliance”?
- I found issues- what should I do?
- What to Expect When Inspected
- Q & As



What means to be “in compliance”?



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Are your records in order?

CREATE A DEA AND/OR GDNA READY BINDER

You are required by law to have records that are readily retrievable. CI-II records should be separate from CIII-V records. Dangerous Drug records should be separate from CS records.

Your READY BINDERS should always be well organized and available during an unannounced inspection. All records must be stored at the registered location unless written consent is given from the agency.

Find it at [GDNA/DEA Ready Binder](#)

DEA READY BINDER

Find the forms listed below at our [website](#)

***Controlled Substance (CS) I and II records should be kept separate from CS III to IV records**

Registration Information Section	In Binder (Yes/No)
Current DEA Registration	
Any and all State/Local licenses (Georgia Board of Pharmacy license, Certificate of Occupancy if applicable)	
Emory University Employee and Agent Screening Statement (Form 3)	
Controlled Substance Authorized User Signature Log (Form 4)	
Supplier List (Name, DEA #, Address, Phone Number)	
Destruction Company Info (Name, DEA #, Address, Phone Number)	
Due Diligence Policy (SOP for detecting, preventing, reporting drug	

GDNA READY BINDER

Find the forms listed below at our [website](#)

***Dangerous & Prescription Drug records should be kept separate from Controlled Substance records**

Registration Information Section	In Binder (Yes/No)
Copy of your current Georgia Board of Pharmacy License	
Copy of your protocol	
Emory University Employee and Agent Screening Statement (form 3)	
Supplier List	

Security Section	In Binder (Yes/No)
Room Floor Plan (drawing/layout of room)	
Written description of room security (room access)	
Dangerous Drug Authorization Log (Form A)	
Any safe/cabinet information (dimensions, Lock info, picture of	

Available tools on RCRA/ORIC Website!

You can self-audit your program using the following forms:

- For Controlled Substances: [Form 1: Controlled Substances Self-Inspection \(DOCX\)](#) -
- For Dangerous Drugs: [Dangerous Drugs Self-Inspection \(DOCX\)](#)

These forms have been created to help ensure that all aspects of your program are considered when self-inspecting your drug use. But don't just check the "yes" box. Review that you have all the records, and they are in order

Controlled Substances:

- [DEA Schedule I Pre-inspection checklist](#)
- [SOP for the Report of Loss or Theft of Controlled Substances](#) (Due Diligence Security Process) PDF
 - Please save this with your records before your pre-inspection
- [Investigator Checklist for the Use of Schedule \(DOCX\)1 Controlled Substances](#)
- [Form 1: Controlled Substances Self-Inspection \(DOCX\)](#)- UPDATED 8/27/24
- [Form 2: Controlled Substance Access and Key Log \(DOCX\)](#)- UPDATED 8/26/24
- [Form 3: Emory University Employee and Agent Screening Statement \(DOCX\)](#)- NEW 1/30/24
- [Form 4: Controlled Substance Destruction Log- NEW 1/30/24](#)
- [Form 5: Controlled Substances Discrepancy and Incident Report Form \(DOCX\)](#)- NEW 1/30/24
- [Form 6: Controlled Substances Inventory \(DOCX\)](#). - NEW 1/30/24. This form contains the following forms:
 - 6A- Initial Inventory before receiving drug but after receiving the DEA license
 - 6B- Annual or Biennial Inventory
 - 6C: Prescription Controlled Substances Inventory (Buprenorphine ER/SR)
- [Form 7: Controlled Substance Current Use Log \(DOCX\)](#) UPDATED 1/30/24
- [Form 8: Order/Receipt Log for Schedules I & II Controlled Substances \(DOCX\)](#)
- [Form 9: Order/Receipt Log for Schedules III - V Controlled Substances \(DOCX\)](#)
- [Form 10: DEA Power of Attorney \(PDF\)](#)
- [Form 11: Controlled Substance Dilution Use Log \(DOCX\)](#)- UPDATED 1/30/24
- [Form 12: Chain of Custody \(DOCX\)](#)
- [Form 13: Use and Disposition Log Prescription \(DOCX\)](#)
- **Internal Transfer Requests- [Use this form](#) and contact oric@emory.edu to discuss your internal transfer plan.**

Dangerous Drugs:

- [Dangerous Drugs Self-Inspection \(DOCX\)](#)- UPDATED 8/27/24
- [Form A: Dangerous Drugs Access and Key Log \(DOCX\)](#)- UPDATED 3/13/2024
- [Form B: Dangerous Drugs Order/Receipt Log \(DOCX\)](#)-UPDATED 1/30/24
- [Form C: Dangerous Drugs Use \(DOCX\)](#)-UPDATED 1/30/24
- [Form D: Isoflurane Current Use Log \(DOCX\)](#)UPDATED 3/13/2024
- [Form E: Dangerous Drugs Discrepancy and Incident Report Form \(DOCX\)](#)- UPDATED 1/30/24
- [Form F: Dangerous Drug Dilution log](#)-UPDATED 1/30/24
- [Form G: Meloxicam* \(Stock Bottle\) Use Log](#)- UPDATED 3/13/2024
- [Form H: Meloxicam* Dilution Use Log](#)- UPDATED 3/13/2024
- [Form I: Dangerous Drugs Destruction Log- NEW 1/30/24](#)
- **Internal Transfer Requests- [Use this form](#) and contact oric@emory.edu to discuss your internal transfer plan.**

I Found Issues during a Self-Inspection.

What Should I do?



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Errors happen!

- Even in the best of circumstances, errors happen.
- Don't backtrack info or correct if info cannot be verified
- Document Incidences on [Form 5](#) or [Form E](#) (an incident is not a discrepancy.
 - An incident is: I made a mistake on a record and corrected the error, or a spill occurred, and I documented it on a DEA 41 form)
- Discrepancies in inventory should be reported upon awareness, not after an investigation. [DEA FORM 106](#) [Form E.](#)
- Work on a Corrective and Preventive Action (CAPA) Plan, and make sure to check its implementation
- Contact ORIC for help

CAPA PLANS

- Every Incident or Discrepancy Report should have a CAPA
- Ensure your CAPA is up to date, and that it is working
- Take CS/DD trainings, attend webinars
- Inventory your drugs
- Ask for help!



Audits taking place at Emory

- Currently, we have GDNA agents (associated with GBP) conducting inspections in several labs around the University.
- All who will be inspected received an email from our office with the request to fill a form to provide information.
- If you are interested in learning how to be “inspection ready” check our webinar recording from yesterday at <https://rcra.emory.edu/oric/controlled-substances/training.html>

Questions?



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